제약회사의 API 공급, 완제품 생산위탁, 완제품구매 계약서에서 원료공급 및 생산 관련 계약조항 영문 샘플

17. MANUFACTURE AND SUPPLY OF CAPTISOL.

17.1 **Supply**.

(a) Subject to the terms and conditions of this Agreement, CyDex agrees to supply to Hospira those quantities of Captisol ordered by Hospira in accordance with Section 3.2 of this Agreement. So long as CyDex is able to deliver Captisol in accordance with the terms of this Agreement, except as provided in Section 3.11 (c) below, Hospira agrees that Hospira and its Affiliates shall during the Term order from CyDex no less than 90% of Hospira and its Affiliates aggregate requirements for Captisol for use in the formulation of Finished

Product to be sold in the Major-Market countries.

(b) The parties hereby agree that [*] is CyDex's Third-Party manufacturer of Captisol as of the Effective Date of this Agreement.

17.2 **Purchase Orders**. Hospira shall periodically submit firm purchase orders for Captisol to CyDex, which purchase orders shall set forth the specific quantities needed, the grade of Captisol required, delivery date and shipping instructions. Such purchase orders shall be submitted to CyDex at least [*] but not more than [*] prior to the required delivery date specified therein. If any purchase order or other document submitted by Hospira hereunder or any other document passing between the parties contains terms or conditions in addition to or inconsistent with the terms of this Agreement, the terms of this Agreement shall control and prevail and the parties hereby agree that such additional or inconsistent terms shall simply be ignored and deemed not to exist, unless they are expressly identified as being additional to or inconsistent with this Section 3.2 and are signed by officers of both parties.

17.3 **Forecasts and Excess Demand**. No later than the First Commercial Sale date, Hospira shall provide to CyDex a [*] forecast of its requirements for Captisol, with the first [*] of such forecast constituting a binding commitment upon Hospira to purchase such quantities under firm purchase orders submitted for the respective applicable [*] in accordance with Section 3.2. The balance of the forecast shall merely represent reasonable good-faith estimates for planning purposes only and shall not obligate Hospira to purchase any such amounts. On a [***] basis, Hospira shall update the forecast. If Hospira fails to provide any updated forecast in accordance with this Section 3.3, the forecast last provided by Hospira shall be deemed to be resubmitted as Hospira's binding forecast for the next succeeding [*] period, and with the same quantity and timing as had been forecasted (or deemed to be forecasted) for the [*] of the prior forecast being repeated as the forecasted quantity and timing for the forecast's [*]. CyDex shall notify Hospira as soon as possible, but in any event within [*] of the receipt of any forecast, if CyDex will be unable to deliver Captisol in accordance with such forecast. CyDex's providing of such notification shall not be interpreted in any manner as relieving CyDex of its obligations under this Agreement, nor shall it prevent Hospira from pursuing any and all rights and remedies Hospira may have based on CyDex's failure to be able to deliver Captisol in accordance with the terms of this Agreement. If any purchase order includes an Excess Demand, then (a) CyDex shall supply

the quantity of Captisol which does not constitute an Excess Demand to Hospira in accordance with Section 3.2, and (b) CyDex shall use commercially reasonable efforts to supply the Excess Demand quantities of Captisol requested by Hospira in its purchase orders as soon as commercially possible.

17.4 **Delivery Terms**.

(a) CyDex agrees to deliver Captisol to Hospira's carrier at a continental United States factory or warehouse designated by CyDex, in accordance with the purchase orders submitted by Hospira in accordance with Section 3.2 (each such delivery to be accompanied by a copy of the purchase order submitted by Hospira that corresponds to such delivery). All Captisol shall be delivered to Hospira using the carrier and in accordance with the delivery schedule specified by Hospira in its purchase orders. Captisol shall be delivered by CyDex to Hospira. CyDex will provide the carrier with proper instructions regarding how to transport the Captisol in conditions which will not adversely affect the Captisol, including ensuring that the shipment is temperature monitored and the Captisol is kept at an appropriate temperature throughout shipment.

(b) If CyDex is unable to deliver the Captisol on the date specified by Hospira, CyDex shall notify Hospira as soon as possible, but in any event within [***] of receipt of the purchase order. CyDex's providing of such notification shall not be interpreted in any manner as relieving CyDex of its obligations under this Agreement, nor shall it prevent Hospira from pursuing any and all rights and remedies Hospira may have based on CyDex's failure to deliver the Captisol in accordance with the terms of this Agreement.

(c) With each shipment of Captisol, CyDex shall, if so requested, provide by reference or otherwise all documentation as is reasonably required by any [*] from time to time in connection with Hospira's research, development, modification, manufacture, importation, exportation, use, promotion, marketing, distribution, packaging, offering for sale, selling, and otherwise commercially exploitation, as applicable, of Captisol or the Finished Product. If such documentation is not supplied Hospira may reject the Captisol.

17.5 **Safety Stock**. Within [*] of CyDex's receipt of the first purchase order from Hospira, CyDex shall establish and maintain a safety stock of at least [*] of Captisol available to Hospira based on Hospira's latest forecast provided under Section 3.3. CyDex shall keep

Hospira reasonably informed of the level of inventory identified as the safety stock and shall notify Hospira in the event any deliveries to Hospira deplete the current safety stock levels.

17.6 **Failure to Supply**.

(a) CyDex shall maintain sufficient capacity to manufacture Hospira's projected needs for Captisol during the Term. If CyDex fails to deliver or anticipates that it will be unable to deliver any quantity of Captisol ordered pursuant to the terms of this Agreement for [*], CyDex will promptly notify Hospira. If CyDex fails to deliver any quantity of Captisol for [*], if such notice is received from CyDex, or if upon request by Hospira CyDex fails to provide adequate assurance of its ability to continue to deliver Captisol as required by the terms of this Agreement, then Hospira in its sole discretion and without impairing or limiting any other rights that Hospira may have under this Agreement or under applicable law, including, without limitation, its rights under Sections 2-609 and 2-610 of the Uniform Commercial Code, shall have the right to agree to a revised delivery date or Hospira may: [***] above, CyDex shall assist Hospira, if so requested by Hospira, by [*].

(d) Alternate Manufacturers. If CyDex fails to supply to Hospira, or if CyDex will be unable to supply Hospira with [***]% or more of the quantity of Captisol properly forecasted and ordered by Hospira in accordance with this Agreement, for a period of [*] then CyDex shall immediately provide written notice to Hospira of the [*]. In the event of a [*] in addition to any other rights and remedies Hospira may have under this Agreement, or in equity, or at law:

17.7 **Inspection and Acceptance**.

(a) CyDex shall test and inspect each lot of Captisol for compliance with Specifications prior to the release and shipment thereof to Hospira. CyDex will provide a Certificate of Analysis with each shipment of each lot of Captisol signed by the responsible quality official of CyDex. This Certificate of Analysis must include the results (whether numerical or otherwise) for each test performed that verifies that the Captisol is in compliance with the Specifications, as well as a statement that the subject lot was manufactured in accordance with the appropriate DMF/CEP. To the extent that any reference standard material is delivered to Hospira along with any shipment of Captisol as a result of Hospira's request

for such material pursuant to Section 3.2 of this Agreement, the Certificate of Analysis shall also include specifications on such material for each criterion listed in Exhibit B hereto, which specifications shall meet or exceed the Specifications.

(b) Hospira may test and inspect the Captisol after receipt and either accept or reject it. Captisol may be rejected if it does not comply with the Specifications or is otherwise defective. Hospira will be deemed to have accepted the Captisol, except as to latent defects which are not reasonably discoverable, if Hospira fails to give notice of rejection within [*] after receipt by Hospira of such Captisol. The written notice of rejection shall be given to CyDex and shall include identification of the lot number and description of the Specification failure or other defect.

(c) Following receipt of written notice of rejection of a particular lot of Captisol, in addition to any other rights or remedies Hospira may have under this Agreement, in equity, or at law, CyDex shall, at Hospira's option, provide a credit, refund or prompt replacement of Captisol to Hospira; provided, however, that if CyDex does not agree with Hospira's claim of noncompliance with Specifications or other defect, then the parties shall designate a

mutually acceptable Third Party laboratory to make a determination on such matter from a sample obtained from the batch or other quantity shipped to Hospira. The decision of the Third Party laboratory shall be binding on all parties hereto and all expenses related to such Third Party investigation shall be borne by the party found to have been mistaken. Should such Third Party laboratory confirm Hospira's claim, CyDex shall, at Hospira's request, promptly provide Hospira with a credit, refund or prompt replacement of Captisol to Hospira.

(d) Hospira shall return any rejected Captisol to CyDex at CyDex's expense to an address that CyDex may designate within [*] of CyDex receiving written notice of rejection; provided, however, that if CyDex does not agree with Hospira's claim of noncompliance with Specifications or other defect, Hospira shall not be obligated to return the rejected Captisol to CyDex until [*] after a final determination is made by a Third Party laboratory that such Captisol does not comply with Specifications or is otherwise defective as provided in subparagraph (c) above. Absent such designation of address, Hospira will ship rejected Captisol to CyDex's facility at [*], or such other address as CyDex may previously have given written notice of to Hospira as being the default address for return of rejected Captisol. All freight, insurance and other costs of such shipment along with any risk of loss shall be

borne by CyDex, and shipment will be made from Hospira's designated plant.

(e) Hospira's rights of rejection, return, refund and replacement set forth in this Section 3.7 shall not apply to any Captisol that is non-conforming due to damage that occurs after delivery of such Captisol to Hospira's carrier at the point of origin that is caused by Hospira, any of its Affiliates' or their respective employees or agents' negligence or willful misconduct, including but not limited to, misuse, neglect, improper storage, transportation or use beyond any dating provided.

17.8 **Quality Agreement**. The parties shall on the Effective Date enter into a separate Quality Agreement, in the form attached hereto as Exhibit D. The parties shall comply with the terms of the Quality Agreement, and any breach of the Quality Agreement shall be deemed a breach of this Agreement.

17.9 **Quality Assurance**. Each lot of Captisol to be supplied to Hospira hereunder shall be subject to a quality assurance inspection by CyDex in accordance with CyDex's then current quality assurance standards and the Quality Agreement, which standards shall be designed

to ensure that the Captisol meets the requirements of the Specifications and is manufactured per Good Manufacturing Practices.

17.10 **Process Change Provisions and Procedure**.

(a) General. To the extent pertaining to Captisol to be delivered pursuant to this Agreement, all modifications, changes, additions or deletions to the (i) Specifications; (ii) changes in the expiration period for Captisol; (iii) composition or source of any raw material for Captisol; (iv) method of producing, processing or testing Captisol; (v) change in subcontractors for producing, processing or testing Captisol; or (vi) site of manufacture for Captisol, which CyDex intends to carry out must be evaluated and documented by CyDex. [*], CyDex shall if so required amend its DMF/CEP through the appropriate notification to the FDA and any other applicable Regulatory Authorities. [*].

(b) Required Changes. Any changes relating to the Specifications or manufacturing processes for Captisol hereunder that are required by any applicable laws or other Regulatory Authority requirements in any Major Market, or by medical concerns related to the toxicity, safety and/or efficacy of Captisol shall hereinafter be referred to as "Required

Changes". The parties shall cooperate in making such changes promptly.